

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**IN RE PLAVIX® MARKETING,  
SALES PRACTICE AND PRODUCTS  
LIABILITY LITIGATION (NO. II)**

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**UNITED STATES OF AMERICA, ET  
AL. V. BRISTOL-MYERS SQUIBB  
COMPANY, ET AL.**

) ) MDL DOCKET NO. 2418

) )

) )

) ) CASE NO. 3:13-CV-01039-FLW-

) ) LHG

) ) MOTION DAY: APRIL 15, 2013

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**MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR  
RECONSIDERATION OF THE TRANSFEROR COURT'S JANUARY 30,  
2013 ORDER GRANTING IN PART AND DENYING IN PART  
DEFENDANTS' MOTION TO DISMISS**

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## I. INTRODUCTION

Defendants' Motion for Reconsideration ("Motion") is nothing more than an improper attempt to appeal Judge Herndon's well-reasoned decision denying their Motion to Dismiss. Although Defendants had multiple opportunities to raise supposed "fundamental legal errors," they failed to do so at every turn—that is until this late hour, more than a month after Judge Herndon properly denied their Motion. Defendants failed to file a reply,<sup>1</sup> failed to file a motion for reconsideration in the Southern District of Illinois,<sup>2</sup> and, after Plaintiffs agreed not to argue timeliness if Defendants filed a motion for reconsideration in this Court within three days after the opening of a docket in this matter, even failed to file

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<sup>1</sup> In the Southern District of Illinois, "reply briefs are not favored and should only be filed in exceptional circumstances." Dkt. No. 54 at 12 n.8 (quoting SDIL-LR 7.1(c)(2)). Instead of filing a reply, however, Defendants filed an opposition to Relator's request for expedited ruling on the Motion to Dismiss, which declined to cite any exceptional circumstances. Accordingly, Judge Herndon concluded that "[w]hile [D]efendants' opposition to expedited ruling would have provided [D]efendants the perfect opportunity to indicate what exceptional circumstances warrant a reply, they chose not to do so." *Id.*

<sup>2</sup> Defendants also could have filed their Motion on any of the 13 days between Judge Herndon's decision and the MDL transfer order. They chose not to, knowing full well (given their extensive practice in this district) that the transferee court (that they requested to the JPML) allows only 14 days for the filing of a motion for reconsideration. *See L. Civ. R. 7.1(i).* In essence, Defendants voluntarily created the "unusual circumstances" that purportedly justified their request for an extension. *See* Dkt. No. 70, at 1.

within this Court's three-day extension.<sup>3</sup> This Court should not reward Defendants' missteps by granting their Motion, particularly where Defendants have not provided a single controlling decision showing that Judge Herndon made a clear error of law.

## **II. ARGUMENT**

The Motion implies that this Court grants motions for reconsideration as a matter of course. That is not so. “[R]econsideration is ‘an extraordinary remedy’ that is to be granted ‘very sparingly.’” *Wade v. Colaner*, No. 3:06-cv-3715, 2009 WL 1738490, at \*1 (D.N.J. June 17, 2009) (Wolfson, J.) (quoting *Interfaith Cnty. Org. v. Honeywell Int'l, Inc.*, 215 F. Supp. 2d 482, 507 n.12 (D.N.J. 2002)). “It is well-established that a court may only grant a motion for reconsideration if the movant can show: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not previously available; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.” *Adamson v. Ortho-McNeil Pharm., Inc.*, No. 06-866 (FLW), 2007 WL 604790, at \*2 (D.N.J. Feb. 20, 2007) (Wolfson, J.) (citing *Max’s Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999)). And, as this Court has recognized, if “reconsideration is sought based upon the third factor, the movant may address

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<sup>3</sup> Although Defendants specifically requested a *three-day* extension from the opening of a docket in this district, they waited *four* days to file their Motion. Dkt. No. 70.

*only matters that were presented to the Court, but were not considered by the Court in making the decision at issue.”* *Adamson*, 2007 WL 604790, at \*2 (emphasis added) (citing *United States v. Compaction Sys. Corp.*, 88 F. Supp. 2d 339, 345 (D.N.J. 1999)).

Here, Defendants only assert that Judge Herndon’s opinion contains “fundamental legal errors.”<sup>4</sup> Consequently, Defendants must set forth “concisely” the “controlling decisions which [they believe Judge Herndon] . . . has overlooked.” L. Civ. R. 7.1(i). Where are these controlling decisions? To ask is to answer. There are none. Defendants fail to cite even a single case mandating a different result.<sup>5</sup> For this reason alone, the Motion should be denied. *See, e.g., P. Schoenfeld Asset Mgmt., LLC v. Cendant Corp.*, 161 F. Supp. 2d 349, 353 (D.N.J. 2001) (denying a motion for reconsideration where plaintiffs “reference[d] no case to support their contention”); *Egloff v. N.J. Air Nat’l Guard*, 684 F. Supp. 1275, 1279 (D.N.J. 1988) (denying a motion for reconsideration where a plaintiff failed to cite any pertinent case law that the court might have overlooked).

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<sup>4</sup> Dkt. No. 72-1, at 1-2. Because Defendants did not (and could not) argue that there has been an intervening change in controlling law or the availability of new evidence that was not previously available, Plaintiffs do not address these grounds that could (but here, do not) support a motion for reconsideration.

<sup>5</sup> Interestingly, Judge Herndon also found that Defendants failed to provide contrary precedent: “While defendants seem to argue [R]elator’s theory of recovery is foreclosed in the Seventh Circuit, defendants have not produced authority binding on this Court that conclusively demonstrates as such, nor has this Court’s independent search revealed the same.” Dkt. No. 54, at 5.

Defendants simply disagree with Judge Herndon's opinion. Indeed, the thrust of their Motion is identical to a principal issue expressly considered by Judge Herndon—whether “Defendants are liable for causing the government to pay for Plavix prescriptions that doctors wrote for FDA-approved, ‘on-label’ indications.”<sup>6</sup> Judge Herndon rejected Defendants’ arguments, holding (with respect to Medicare) that “[a]s a prerequisite to Medicare payment, the particular item or service must be ‘reasonable and necessary,’” and “the fact that a drug is FDA-approved, does not mean it is ‘reasonable and necessary’ in every instance it is prescribed.”<sup>7</sup> Thus, “[a]ccepting [R]elator’s allegations as true, . . . [D]efendants’ fraudulent actions caused physicians and pharmacists to submit claims for reimbursement of prescribed treatment that [were] not ‘reasonable and necessary’ and [were] thus false.”<sup>8</sup>

With respect to Medicaid, Judge Herndon similarly rejected Defendants’ argument, albeit without explanation, holding that “the second amended complaint . . . sufficiently alleges actionable claims” with respect to all claims except the fourth cause of action, the dismissal of which is not now at issue.<sup>9</sup> Thus, contrary to Defendants’ bald assertions, Judge Herndon never applied the

<sup>6</sup> Dkt. No. 72-1, at 2.

<sup>7</sup> Dkt. No. 54, at 4-5.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 2 & n.2. Notably, “[t]he court is not required to state findings or conclusions when ruling on a motion under Rule 12.” Fed. R. Civ. P. 52(a)(3).

“reasonable and necessary” standard to Medicaid services. Rather, he simply concluded that, if true, Relator’s allegations—“that defendants knowingly provided false information regarding the efficacy of Plavix compared to cheaper alternatives, which caused physicians and pharmacists to either expressly or impliedly make false certifications about Plavix’s efficacy or necessity for the patient’s treatment”—constitute false claims for payment by government payors.<sup>10</sup>

Defendants may not now complain that Judge Herndon got it wrong, particularly without any controlling support. “Indeed, a ‘party seeking reconsideration must show more than a disagreement with the court’s decision,’ . . . and will fail to meet its burden if it merely presents ‘a recapitulation of the cases and arguments considered by the Court before rendering its original decision.’” *Purpura v. Buskin, Gaims, Gains, Jonas & Stream*, No. 08-2974 (FLW), 2008 WL 5272859, at \*2 (D.N.J. Dec. 16, 2008) (Wolfson, J.) (quoting *Panna v. Firsttrust Sav. Bank*, 760 F. Supp. 432, 435 (D.N.J. 1991); *Elizabethtown Water Co. v. Hartford Cas. Ins. Co.*, 18 F. Supp. 2d 464, 466 (D.N.J. 1998)). Defendants have not satisfied this high burden. Instead, they are attempting an impermissible appeal.

“It is improper on a motion for reconsideration to ‘ask the Court to rethink what it had already thought through . . . .’” *Sheehan v. Dobin*, No. 10-6288

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<sup>10</sup> Dkt. No. 54, at 4.

(FLW), 2012 WL 426285, at \*2 (D.N.J. Feb. 9, 2012) (Wolfson, J.) (quoting *Oritani Sav. & Loan Ass'n v. Fidelity & Deposit Co.*, 744 F. Supp. 1311, 1314 (D.N.J. 1990)). This is particularly true here, where it is not Judge Herndon that is being asked to reconsider his own decision. Notably, “nothing in the text of 28 U.S.C. § 1407, the Multidistrict litigation transfer statute, . . . authorizes a transferee judge to vacate or modify an order of a transferor judge.” *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 440 (3d Cir. 2009) (footnote omitted). Otherwise, “litigation could begin anew with each MDL transfer,” and Congress did not intend “that a ‘Return to Go’ card would be dealt to parties involved in MDL transfers.” *Id.* at 441. Thus, in only the most limited circumstances can a transferee judge modify a transferor judge’s order. Here, reconsideration of Judge Herndon’s Order is not “necessary to harmonize activity relating to discovery,” and, therefore, this Court should not tolerate Defendants’ blatant attempt to take a second bite at the apple. *Id.* at 442 (citation omitted).

Finally, this Court “will only grant [a motion for reconsideration] if the matters overlooked might reasonably have resulted in a different conclusion.” *Purpura*, 2008 WL 5272859, at \*2 (citing *Bowers v. Nat'l Collegiate Athletic Assoc.*, 130 F. Supp. 2d 610, 613 (D.N.J. 2001)). Here, even if Judge Herndon *overlooked* controlling authority (which he did not and Defendants have not shown otherwise), the law bears out Judge Herndon’s decision. Defendants’ improper

promotion of Plavix caused physicians to falsely certify that prescriptions of the drug met the qualifications for coverage (under various government programs) when they did not. This constitutes false claims actionable under the FCA.

**A. MEDICARE ONLY PAYS FOR PRESCRIPTION DRUGS THAT ARE “REASONABLE AND NECESSARY.”**

Defendants argue that “Medicare Part D plans must reimburse any ‘covered Part D drug’”—even when the drugs are neither reasonable nor necessary.<sup>11</sup> They are wrong. Defendants’ argument ignores the plain fact that not all “covered Part D drugs” are reasonable and necessary, and that the Medicare statute explicitly permits plans to refuse to pay for drugs unless they are both “covered Part D drugs” *and* reasonable and necessary.<sup>12</sup> In a section titled “general exclusion provisions,” Congress specifically authorizes prescription drug plans to “*exclude* from qualified prescription drug coverage any *covered [P]art D drug*” that is not reasonable and necessary.<sup>13</sup> 42 U.S.C. § 1395w-102(e)(3)(A) (emphasis added).<sup>14</sup>

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<sup>11</sup> Dkt. No. 72-1, at 3-5.

<sup>12</sup> Just because a drug is “FDA-approved” does not mean that it is “reasonable and necessary.” *See, e.g., Almy v. Sebelius*, 749 F. Supp. 2d 315, 330 (D. Md. 2010) (explaining that FDA clearance or approval does not automatically guarantee Medicare coverage, noting “the FDA and CMS are independent entities with different agendas and statutory mandates”).

<sup>13</sup> Importantly, just because a benefit is generally available does not mean that all plan members are eligible to receive the benefit. *See* Thomas R. Barker, *The Low-Income Subsidy in the New Medicare Drug Benefit*, 1 J. Health & Biomedical L. 49, 82 n.28 (2005) (“As always under the Medicare program, the availability of a benefit category does not mean that a beneficiary can obtain the

Given this clear language, it defies logic to suggest (as Defendants do) that “Medicare Part D plans must reimburse any ‘covered [P]art D drug.’”<sup>15</sup>

Indeed, all but Defendants agree that Medicare does not pay for prescription drugs unless they are reasonable and necessary. For example, Centers for Medicare and Medicaid Services (“CMS”) instructs physicians that “Part D drugs must be prescribed” in accordance with the “reasonable and necessary” standard.<sup>16</sup> In addition, multiple courts have applied the “reasonable and necessary” standard to Medicare Part D.<sup>17</sup> Even legal scholars have recognized that the “reasonable and necessary” standard applies to Medicare Part D.<sup>18</sup>

To the extent Defendants are suggesting that Medicare plans have opted to pay for drugs that Congress has said they do not have to cover—thereby absolving Defendants of their improper conduct—Defendants are again wrong. Medicare

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benefit; a Medicare benefit generally is only available if it is ‘reasonable and necessary’ to treat the beneficiary’s medical condition.”).

<sup>14</sup> Section 1395w-102(e)(3)(A) adopts the “reasonable and necessary” criteria that applies to Medicare Parts A and B under 42 U.S.C. § 1395y(a).

<sup>15</sup> Dkt. No. 72-1, at 3-5.

<sup>16</sup> Centers for Medicare and Medicaid Services, Instructions: Requirements for Submitting Prescription Drug Event Data 20 (2006).

<sup>17</sup> See *Kilmer v. Leavitt*, 609 F. Supp. 2d 750, 751 (S.D. Ohio 2009) (“A Part D plan sponsor need not provide coverage for a Part D drug that is not reasonable and necessary for circumstances specified in the statutory framework or that is not prescribed in accordance with the plan or the Medicare Act.”); *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 409 (D. Mass. 2010) (stating that Medicare outpatient prescription drug benefits are governed by section 1395w-102(e), which contains the reasonable and necessary guidelines).

<sup>18</sup> See Barker, *supra* note 13, at 82 n.28 (“The ‘reasonable and necessary’ standard applies for purposes of Part D.”).

Part D administrators are not shy about reminding their members that the plans only cover drugs that are reasonable and necessary. CIGNA, for example, tells its members that it “will generally cover a drug on the plan’s Drug List *as long as . . . the drug is medically necessary, meaning reasonable and necessary for treatment of your illness or injury.*”<sup>19</sup> Because Part D plan sponsors (such as CIGNA) routinely deny coverage for unreasonable or unnecessary drugs, CMS requires such sponsors to designate a physician responsible for reviewing denials of coverage under this overarching standard.<sup>20</sup> This physician would be wholly unnecessary if Part D plans paid for unreasonable or unnecessary drugs.

In the event Defendants are arguing that the “reasonable and necessary” standard (and therefore, Relator’s false claims) should be overlooked because some plan administrators mechanistically pay for drugs if they are “on the plan,” Defendants are wrong again. The fundamental purpose of the FCA is to recover monies that the government reimbursed as a result of fraudulent conduct.<sup>21</sup> Simply

<sup>19</sup> CIGNA Medicare Rx Plan One (PDP), ch. 3, § 3.1, *available at* [http://www.q1medicare.com/2011/content/includes/pdpPlanMaterials/CIGNA-2011\\_PDP\\_EvidenceOfCoverage\\_PlanOne.pdf](http://www.q1medicare.com/2011/content/includes/pdpPlanMaterials/CIGNA-2011_PDP_EvidenceOfCoverage_PlanOne.pdf) (last visited Mar. 17, 2013) (emphasis added).

<sup>20</sup> Centers for Medicare and Medicaid Services, Prescription Drug Benefit Manual, § 70.6, *available at* <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/partdmanualchapter18.pdf> (last visited Mar. 25, 2013).

<sup>21</sup> See *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (“The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers; the False

because a Part D plan has reimbursed claims for Plavix does not mean that such claims were properly payable in all instances. Here, Defendants' misrepresentations deprived physicians of the opportunity to "make considered medical judgments." *Strom ex rel. United States v. Scois, Inc.*, 676 F. Supp. 2d 884, 895 n.2 (N.D. Cal. 2009). Defendants' misrepresentations "left many physicians with the false impression that Plavix was essentially the *only option* for effective patient care in a host of contexts,"<sup>22</sup> thereby causing physicians to write prescriptions for Plavix even when the drug was not reasonable and necessary given cheaper, safer, and more effective options, like aspirin. As the Northern District of California held, "a prescription . . . in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement," and therefore, constitute a false claim. *Id.* at 891.

Accordingly, however Defendants' arguments are characterized, they fail to cast even the slightest doubt on Judge Herndon's well-reasoned opinion. Accepting Relator's allegations as true and drawing all reasonable inferences in her favor, Relator has set forth cognizable claims under the FCA with respect to Medicare Part D.

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Claims Act does this by insisting that person who send bills to the Treasury tell the truth.").

<sup>22</sup> Dkt. No. 38 ¶ 62 (emphasis added).

**B. MEDICAID ONLY PAYS FOR DRUGS THAT ARE “MEDICALLY NECESSARY.”**

Defendants’ Medicaid arguments are similarly flawed. Without support, they argue that “drugs ‘approved for safety and effectiveness’ by the FDA and prescribed for an FDA-approved use *must* be covered.”<sup>23</sup> Not so. The requirement that a drug be a “covered outpatient drug” is just one prerequisite to payment coverage. “Once services are covered, the next issue is whether the covered service is medically necessary.” *Hunter v. Chiles*, 944 F. Supp. 914, 921 (S.D. Fla. 1996). This is because the federal government authorizes state Medicaid agencies to “place appropriate limits on a service based on such criteria as medical necessity.” 42 C.F.R. § 440.230(d); *Hunter*, 944 F. Supp. at 921. All have done so.

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<sup>23</sup> Dkt. No. 72-1, at 2-3 (citations omitted). Not one of the sources cited by Defendants mandates reimbursement for all covered outpatient drugs. See 42 U.S.C. § 1396r-8(a)(1), (3) (explaining situations where payment is *available* under Medicaid); 42 U.S.C. § 1396b(i)(10) (providing that payment “shall not be made” under certain circumstances); 42 U.S.C. § 1396r-8(k)(2)(A)(i) (defining “covered outpatient drug”); 42 U.S.C. § 1396r-8(k)(6) (defining “medically accepted indication”); 42 U.S.C. § 1396r-8(d)(1)(A) (“A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).”); 42 U.S.C. § 1396r-8(d)(1)(B) (providing a *non-exclusive* list of permitted exclusions for covered outpatient drugs); *In re Vioxx Prods. Liabl. Litig.*, MDL No. 1657, 2010 WL 2649513, at \*10-11 (E.D. La. June 29, 2010) (examining Louisiana’s Medicaid program and determining whether Louisiana could deny reimbursement for Vioxx *entirely*, without ever addressing the “medically necessary” standard).

South Carolina’s Medicaid agency, for example, “will pay for a service when the service is covered . . . and is medically necessary.”<sup>24</sup> Kansas’s Medicaid agency will “not reimburse a provider for the provision of a service. . . unless the provision of the service was medically necessary.”<sup>25</sup> New Mexico’s Medicaid agency “reimburses providers for furnishing covered services to medicaid recipients only when the services are medically necessary.”<sup>26</sup> Massachusetts’s Medicaid program “will not pay a provider for services that are not medically necessary and may impose sanctions on a provider for . . . prescribing a service . . . that is not medically necessary.”<sup>27</sup> Arizona’s regulations define “pharmaceutical services” to include only “medically necessary medications that are prescribed by a physician.”<sup>28</sup> And in Montana, prescribed drugs “may only be those that are medically necessary and that are the most efficient and cost-effective.”<sup>29</sup> The list goes on.<sup>30</sup>

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<sup>24</sup> S.C. Health & Human Servs., S.C. Health Connections (Medicaid) Provider Manual, Pharmacy Servs. (Feb. 1, 2005, updated Mar. 1., 2003) § 1, at 1-10; S.C. Code Ann. Regs. 126-301.

<sup>25</sup> Kan. Admin. Regs. §§ 30-5-63; 30-5-92(a).

<sup>26</sup> N.M. Admin. Code §§ 8.302.5.10; 8.301.2.9.

<sup>27</sup> 130 Mass. Code Regs. 450.204; 450.101.

<sup>28</sup> Ariz. Admin. Code § R9-22-101.

<sup>29</sup> Mont. Code Ann. § 53-6-101(9); 53-6-101(4)(h).

<sup>30</sup> See, e.g., Alaska Admin. Code tit. 7, § 105.100; Ark. Medicaid Program Provider Manual, § 142.100, [https://www.medicaid.state.ar.us/Download/provider/provdocs/Manuals/SectionI/Section\\_I.doc](https://www.medicaid.state.ar.us/Download/provider/provdocs/Manuals/SectionI/Section_I.doc); Conn. Agencies Regs. § 17b-192-6; D.C. Dep’t of Health Care Fin., D.C. Medicaid Fee-for-Service Member Handbook 13-14, <http://dhcf.dc.gov/sites/default/files/dc/sites/dhcf/publication/attachments/>

Whether a prescription drug is medically necessary<sup>31</sup> is decided in the first instance by the treating physician. *See Smith v. Rasmussen*, 249 F.3d 755, 759 (8th

DHCF %20FFS%20Medicaid%20Version%2013\_red.pdf; Del. Health and Soc. Servs. Div. of Medicaid & Med. Assistance, Del. Med. Assistance Program Gen. Policy, § 1.27.3.1 (2013), <http://www.dmap.state.de.us/downloads/manuals/General.Policy.Manual.pdf>; Fla. Stat. Ann. § 409.905; Haw. Code R. § 17-1737-84; Idaho Admin. Code r. 16.03.09.662(01); Ill. Dep’t of Healthcare and Family Servs., Handbook for Providers of Med. Servs., § 104 (2009), <http://www.hfs.illinois.gov/assets/100.pdf>; Ind. Code. § 12-15-21-3; 907 Ky. Admin. Regs. § 1:019(1)(3); La. Rev. Stat. Ann. § 46:437.11(B); 10-144 Me. Code R. ch. 101, ch. II, § 80; Mich. Dep’t of Cnty. Health, Medicaid Provider Manual, § 8.3, <http://www.mdch.state.mi.us/dchmedicaid/manuals/MedicaidProviderManual.pdf>; Miss. Admin. Code § 23-200:5.1; 471 Neb. Admin. Code, ch. 1 § 002; Okla. Admin. Code § 317:30-3-1(f); Or. Admin. R. 410-120-1200; 55 Pa. Code § 1121.11; S.D. Admin. R. 67:16:01:06.02; Tenn. Code Ann. § 71-5-144; Tex. Medicaid Provider Procedures Manual, § 1.6.8, [http://www.tmhp.com/TMHP\\_File\\_Library/Provider\\_Manuals/TMPPM/2013/Mar2013\\_TMPPM.pdf](http://www.tmhp.com/TMHP_File_Library/Provider_Manuals/TMPPM/2013/Mar2013_TMPPM.pdf); Utah Admin. Code r. 414-10; Vt. Agency of Human Servs., Provider Manual 33, 47, <http://www.vtmedicaid.com/Downloads/manuals/New%20Consolidated%20Manal/ProvManual%20Consolidated%203-1-13.pdf>; Wash. Admin. Code § 182-501-0050(4); Wis. Admin. Code DHS § 106.02.

<sup>31</sup> In Massachusetts, for example, a service, including a prescription drug, cannot meet the “medically necessary” requirement unless there is “no other medical service . . . comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency.” 130 Mass. Code Regs. 450.204(A)(2). In Connecticut, “medically necessary” services are those that are “not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results.” Conn. Gen. Stat. Ann. § 17b-259b. *See also* Del. Health and Soc. Servs. Div. of Medicaid & Med. Assistance, Del. Med. Assistance Program Gen. Policy, § 13.0, Appendix H (2013), <http://www.dmap.state.de.us/downloads/manuals/General.Policy.Manual.pdf> (defining “medically necessary” to mean “the least costly, appropriate, available health service alternative . . . represent[ing] an effective and appropriate use of program funds”); Miss. Admin. Code § 23-200:5.1 (defining “medically necessary” to mean health care services where “[t]here is no other effective and more conservative or substantially less costly treatment service and setting available”); 471 Neb. Admin. Code, ch. 1 § 002 (defining “medical

Cir. 2001) (“[T]he Medicaid statute and regulatory scheme create a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment.” (quoting *Weaver v. Reagen*, 886 F.2d 194, 200 (8th Cir. 1989))); *see also* Wyo. Admin. Code HLTH MDCCD Ch. 1 § 3 (stating that a prescription is an “order . . . from a practitioner that a certain drug . . . is medically necessary”); N.D. Admin. Code 75-02-02-09.4 (providing that covered medical services or supplies “are medically necessary when determined so by the medical provider”). Defendants’ misrepresentations about the efficacy of Plavix when compared to aspirin deprived physicians of the opportunity to make this decision based on accurate information.<sup>32</sup> The result: Defendants caused countless physicians to prescribe Plavix when Plavix was not “medically necessary,” and therefore, not covered by Medicaid.<sup>33</sup> The resulting Medicaid claims are false

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necessity” to mean supplies “[r]endered in the most cost-efficient manner”); S.D. Admin. R. 67:16:01:06.02 (“To be medically necessary, the covered service must . . . [have] no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly.”); Utah Admin. Code r. R414-1-2 (18) (defining “medically necessary service” to mean that “there is no other equally effective course of treatment available or suitable for the recipient requesting the service that is more conservative or substantially less costly”); Wash. Admin. Code § 182-500-0070 (defining “medically necessary” to mean that “[t]here is no other equally effective, more conservative or substantially less costly course of treatment available”); Wyo. Admin. Code HLTH MDCCD Ch. 26 § 4 (defining “medically necessary” to mean the service is “[p]erformed in the most cost effective and appropriate setting required by the recipient’s condition”).

<sup>32</sup> Dkt. No. 54, at 3-4 (summarizing Relator’s allegations).

<sup>33</sup> *Id.*

claims.<sup>34</sup> See *United States v. Kensington Hosp.*, 760 F. Supp. 1120, 1127 (E.D. Pa. 1991) (“Payment for services [including prescription drugs] not medically necessary clearly constitutes an injury to the government sufficient to withstand a motion to dismiss.”); see also *Strom*, 676 F. Supp. 2d at 891 (holding that a prescription for a drug not meeting the underlying qualifications for federal reimbursement constitutes a false claim).

### **III. CONCLUSION**

For the foregoing reasons, Defendants’ Motion should be denied.<sup>35</sup>

Dated: April 1, 2013.

Respectfully submitted,

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<sup>34</sup> Defendants’ arguments regarding CHAMPUS/TRICARE, CHAMPVA, and FEHBP similarly fail because each program requires that services be medically necessary. See *Exclusions*, TRICARE, <http://www.tricare.mil/CoveredServices/Exclusions.aspx> (last visited March 21, 2013); CHAMPVA Policy Manual, Ch. 1, Sec. 2.1, available at <http://www.va.gov/hac/forbeneficiaries/champva/policymanual/index.asp>; Blue Cross and Blue Shield Service Benefit Plan Section 5(a), 2013, available at <http://www.opm.gov/healthcare-insurance/healthcare/plan-information/plan-codes/2013/brochures/71-005.pdf> (“[A]ll [FEHBP] benefits . . . are payable only when we determine they are medically necessary.”).

<sup>35</sup> Defendants do not appear to be seeking reconsideration of their motion to dismiss in regard to Relator’s state *qui tam* claims. Notably, Judge Herndon declined to entertain Defendants’ motion to dismiss Relator’s state-law claims because Defendants arguments were “too vague to meaningfully address at this time.” Dkt. No. 54, at 10-11. This is not a fundamental legal error.

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